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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,317	09/17/2003	Jeffery D. Snell	A03P1064	6211
36802	7590	03/06/2006	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			SMITH, STEPHANIE R	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/665,317	Applicant(s) SNELL ET AL.	
	Examiner Stephanie Smith	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 20 recites the limitation "the histogram" in "using the histogram." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 8-9, 16, 18, 19, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Marcovecchio (U.S. 2002/0032469). With reference to claim 1, Marcovecchio teaches that QRS complexes are sensed during normal sinus rhythm (NSR) and used to determine a NSR template (see page 1, paragraph 11). Further, the NSR template is an average value computed from the corresponding NSR complex vectors, and the number of NSR complexes used in determining the NSR template is a programmable value in the range of 10 to 100 NSR complexes (see page 4, paragraph 41). With regards to claim 2, the system senses a QRS-complex and morphological features are extracted from the QRS-complexes including the amplitude values of peaks

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and valleys (see page 4, paragraph 39). Referring to claim 3, the system senses QRS-complexes and isolates the complexes as they are sensed (see page 3, paragraphs 38 and 39). Regarding claims 8 and 9, Marcovecchio teaches sensing and using QRS-complexes to determine tachycardia events (see page 1, paragraph 11), but also teaches that P-wave complexes can also be used in the invention (see page 7, paragraph 74).

3. With reference to claims 16 and 19, the system senses a QRS-complex of a tachycardia complex is convolved with a NSR template to determine a tachycardia complex output in order to classify the tachycardia as supraventricular or ventricular (see page 2, paragraph 14). With regards to claims 18 and 21, Marcovecchio teaches an implantable cardiac device that uses a transvenous lead system to allow sensing of the cardiac action potentials (see page 3, paragraph 30). Further, the implantable cardiac device contains a microprocessor, morphology analyzer, and filter output response filter that together process cardiac signals to determine if a tachycardia has occurred (see figure 7 and paragraphs 68-71).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcovecchio in view of Carlson et al (U.S. 2001/0037069). With reference to claim 4, Marcovecchio teaches the detecting of QRS-complexes and averaging them to determine whether a tachycardia has occurred as described above, but do not teach displaying the complexes in the form of a histogram. Carlson et al. teach plotting a histogram with RR intervals on one axis and time difference between successive RR intervals on the other axis (see page 1, paragraph 7). Histograms are useful in interpreting data because the area under the curve of a histogram can be indicative of various health conditions (see page 1, paragraph 10). Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the detecting of QRS-complexes and averaging them to determine whether a tachycardia has occurred as taught by Marcovecchio with the histogram taught by Carlson et al. in order to aid in analyzing the significance of the measured data.

5. Regarding claim 14, Marcovecchio teaches the detecting of QRS-complexes and averaging them to determine whether a tachycardia has occurred as described above, but do not teach a histogram, nor does he teach altering therapy based on the histogram. Carlson et al. teach the histogram as described above, and further teach that based upon analysis of the histogram, the efficacy of a therapy can be analyzed and adjustments can be made to the therapy (see page 3, paragraph 35). The histogram allows the clinician to evaluate the efficacy of a therapy so that periodic adjustments can be made in order to provide the patient with the most effective therapy (see page 3, paragraph 35). Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the detecting of QRS-complexes and averaging them to determine whether a tachycardia has occurred taught by Marcovecchio with the histogram and modification of therapy in order to provide the patient with the most effective therapy.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marcovecchio in view of Carlson et al. as applied to claim 4 above, and further in view of Gessman (U.S. 4340065). Marcovecchio in view of Carlson et al. teach the detecting of QRS-complexes and averaging them to determine whether a tachycardia has occurred and histogram as described above, but do not teach plotting a histogram of counts versus time. Gessman does teach plotting a histogram of counts versus time (see figure 6 and column 10, lines 43-47). Such a plot would allow a physician to easily view how many times an event occurred during a period of time. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to

combine the detecting of QRS-complexes and averaging them to determine whether a tachycardia has occurred and histogram as described above with a histogram plot of counts versus time in order to allow a physician to easily view how many times an event occurred during a period of time.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marcovecchio in view of Carlson et al. as applied to claim 4 above, and further in view of Mannava et al (U.S. 4551018). Marcovecchio in view of Carlson et al. teach the detecting of QRS-complexes and averaging them to determine whether a tachycardia has occurred and histogram as described above, but do not teach plotting a histogram of counts versus amplitude. Mannava et al. do teach plotting a histogram of counts versus amplitude (see figure 8). A histogram of counts versus amplitude enables the clinician to better understand what type of behavior the heart is exhibiting when the R-wave is measured at differing amplitudes. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the detecting of QRS-complexes and averaging them to determine whether a tachycardia has occurred and histogram with a plot of counts versus amplitude so that the clinician could examine what type of behavior the heart is exhibiting at differing amplitudes.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marcovecchio in view of Greenspon et al (U.S. 5954661). Marcovecchio teaches the detecting of QRS-complexes and averaging them to determine whether a tachycardia has occurred as described above, but do not teach acquiring signals indicative of an evoked response. Greenspon et al. teach acquiring and ensemble averaging the

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evoked response (see column 10, lines 51-60). Greenspon et al. teach that ensemble averaging increases the signal-to-noise ratio (see column 10, lines 51-60). Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the detecting of QRS-complexes and averaging them to determine whether a tachycardia has occurred with detecting an evoked response in order to increase the signal-to-noise ratio.

9. Claims 10 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcovecchio in view of Carlson et al. as applied to claim 4 above, and further in view of Koestner et al (U.S. 5300093). Marcovecchio in view of Carlson et al. teach the detecting of QRS-complexes and averaging them to determine whether a tachycardia has occurred and histogram described above, but do not teach a histogram that represents the occurrence of events with respect to time. Koestner et al. teach that the device can sense intracardiac electrograms and at least one physiological parameter, and transmit the combination to an external monitoring device for display and analysis (see Abstract). Koestner et al. further teach that the software within the external monitoring device may draw complete histograms (see column 28, lines 22-23). Koestner et al. further teach that the system may display critical time intervals such as refractory periods and blanking intervals in a manner which expresses the timing relationship of such events to cardiac events (see column 28, lines 45-48). It is obvious if the system displays these periods in such a manner that it is also displaying the time of the cardiac events. A histogram that represented the occurrence of cardiac events with time would allow the physician to view when events are occurring and would

enable the physician to better classify a condition a patient may have. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the detecting of electrogram signals and ensemble averaging and histogram with a representation of events associated with a time in order to enable a physician to better classify a condition a patient may have.

10. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marcovecchio in view of Carlson et al. as applied to claim 4 above, and further in view of Leybovich (WO 99/36769). Marcovecchio in view of Carlson et al. teach the detecting of QRS-complexes and averaging them to determine whether a tachycardia has occurred and histogram as described above, but do not teach a histogram of cardiac events with respect to amplitude. Leybovich does teach a histogram that plots occurrences versus amplitude in a histogram (see Abstract and figures 4, 6, and 8). While the histogram taught by Leybovich does not teach this histogram for cardiac events, a histogram is a form of data manipulation and therefore could be applied to any situation in which an occurrence could be associated with an amplitude. It would be useful to create a histogram of occurrence versus amplitude in order to be able to discern what if any type of arrhythmia is taking place in the patient's heart. Therefore, it would have been obvious at the time the invention was disclosed to combine the detecting of QRS-complexes and averaging them to determine whether a tachycardia has occurred and histogram as described above with the histogram of occurrence versus amplitude in order to discern the behavior of the heart.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marcovecchio in view of Ackmann et al (U.S. 5178154). Marcovecchio teaches the device described above, but does not teach repeating the acquiring of beats and ensemble averaging approximately five times. Ackmann et al. teach that during continuous monitoring, five sets of ensemble averaged data are combined to derive mean values for use in calculating and displaying trends (see column 10, lines 55-58). Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the cardiac device taught by Marcovecchio with the combining of five sets of ensemble averaged data in order to derive mean values for use in calculating and displaying trends.

12. With regards to claim 13, Marcovecchio teaches the device described above, but does not teach repeating the acquiring of beats and ensemble averaging approximately five times. Ackmann et al. teach that during continuous monitoring, five sets of ensemble averaged data are combined to derive mean values for use in calculating and displaying trends (see column 10, lines 55-58). Marcovecchio in view of Ackmann et al. do not disclose expressly that the repeating occurs from approximately ten to approximately 100 times. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to repeat the acquiring 5 times because Applicant has not disclosed that repeating the acquiring from approximately ten to approximately 100 times provides an advantage, is used for a particular purpose, or solves a particular problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with

repeating the acquiring 5 times because both repeating 5 times and repeating 10 to 100 times perform the same function of improving the signal to noise ratio. Therefore, it would have been an obvious matter of design choice to modify Marcovecchio in view of Ackmann et al. to obtain the invention as specified in claim 13.

13. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marcovecchio in view of Carlson et al. as applied to claim 4 above, and further in view of John (U.S. 4974598). Marcovecchio in view of Carlson et al. teach the detecting of QRS-complexes and averaging them to determine whether a tachycardia has occurred and histogram as described above, but do not teach determining if cardiac function is normal or abnormal using the histogram. John teaches an electrocardiographic analysis that determines unusual beat morphologies compared to the normal beat of the patient. The results are displayed using a histogram. The relative probability of various cardiac pathologies is estimated (see Abstract and column 6, lines 36-68, column 7, and column 8, lines 1-20). It would be obvious to use the histogram to determine if cardiac function is normal or abnormal in order to prevent delivering unnecessary treatment. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the detecting of QRS-complexes and averaging them to determine whether a tachycardia has occurred and histogram with determining if cardiac function is normal or abnormal in order to prevent the deliverance of unnecessary treatment.

14. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marcovecchio in view of Koestner et al. Marcovecchio teaches the detecting of QRS-

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complexes and averaging them to determine whether a tachycardia has occurred described above, but does not teach analyzing an intracardiac electrogram using a histogram. Koestner et al. teach that the device can sense intracardiac electrograms and at least one physiological parameter, and transmit the combination to an external monitoring device for display and analysis (see Abstract). Koestner et al. further teach that the software within the external monitoring device may draw complete histograms (see column 28, lines 22-23), and that the graphic channels which may be displayed include intracardiac electrograms (see column 28, lines 23-25). A histogram allows a physician to easily view the behavior of the heart in order to determine if it is functioning properly. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the detecting of QRS-complexes and averaging them to determine whether a tachycardia has occurred with analyzing an intracardiac electrogram in order to determine if the heart is functioning properly.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. 6663572 to Starobin et al. discloses a method for assessing cardiac ischemia by collecting cardiac intervals and comparing them to the time at which a second set of cardiac intervals occurred in order to determine a measure of cardiac ischemia.

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U.S. 5415171 to Goh et al. disclose a method and system for monitoring performance of a heart that includes forming a time series of frames of echocardiographic data.

U.S. 6671548 to Mouchawar et al. discloses a system that classifies cardiac events by determining whether the total of detected events exceeds a corresponding threshold.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Smith whose telephone number is 571-272-2834. The examiner can normally be reached on Monday-Friday between 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


GEORGE R. EVANISKO
PRIMARY EXAMINER

3/2/6

Stephanie Smith 3/2/06